September 9, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.

20/UPI II 34137

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CYANAMID

This Document Does Not Contain 40 CFR Part 158 Data

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October 6, 1997

Mr. Jason Robertson
Chemical Review Manager
Reregistration Branch II
Special Review and Reregistration Division [7508W]
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall, Bldg. #2, Rm. 266A
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Phorate Reregistration - Environmental Fate and Effects Draft Science Chapter; EPA Letter Dated August 6, 1997.

Dear Mr. Robertson:

Thank you for providing American Cyanamid Company with the "final" draft reregistration science chapter for phorate from EPA's Environmental Fate and Effects Division.

As EPA has undertaken the reassessment of organophosphate product tolerances under the mandate of the Food Quality Protection Act (FQPA) and as EPA has conveyed that the FQPA tolerance reassessments will be coordinated with the reregistration process, it appears as though the Reregistration Eligibility Decision (RED) for phorate is imminent. We therefore would like to take this opportunity to point out several general items to you regarding the Agency's Environmental Fate and Effects Division (EFED) science chapter which we feel should be taken into consideration before any RED is finalized. This is especially important when considering the gravity of EFED's recommendation to the Special Review and Reregistration Division (SRRD) which states "consideration be given to the cancellation of the uses of phorate in all but the most extreme circumstances."

Past scheduling at EPA placed phorate behind other products in the RED queue. Agency policy to coordinate the REDs with FQPA-mandated tolerance reassessments has changed the reregistration sequence and it appears as though phorate (as well as several other OP compounds in a "first wave") will receive REDs ahead of when originally scheduled. We are very concerned however that we have not had the opportunity to comprehensively respond to the Agency's draft RED science chapters for phorate and that regulatory decisions may be advanced prematurely due to statutory timing considerations of FQPA and OPP policies rather than scientifically-sound assessment of risk.

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This is unfortunate since although the EFED science chapter for phorate was completed in July of 1996, we did not receive a copy of the EFED chapter until August 11, 1997. We believe our review of and rebuttal to the draft science chapters for phorate is a critical piece of the reregistration process which should not be overlooked as it will help to more truly characterize the risk to man and environment from the use of phorate. Thus, we are planning to respond to the draft science chapters for phorate in a timely fashion via a multi-phase rebuttal beginning with this letter.

Since EPA's EFED is essentially recommending the cancellation of all phorate uses, we will be addressing environmental fate and eco-toxicology issues first in our rebuttals by initially submitting a document meant to convey pertinent information on phorate risk to Agency risk managers. At a June 23, 1997 public meeting meant to address the ecological risk assessment process, Mr. Stephen Johnson, Acting Deputy Office Director of OPP, presented an example of "1000 questions" that risk managers would typically ask risk assessors in order to compose scientifically-sound risk management decisions and put a pesticide and its potential environmental risk into perspective. This type of information was deemed by Mr. Johnson to be instrumental to risk managers in the assessment process. We intend to submit such a characterization of the environmental risk of phorate in early November, 1997. This first document will be followed by a more complete review of the draft EFED science chapter which will be submitted later that same month.

We would also like to point out that although the draft EFED science chapter for phorate was written after the May 1996 FIFRA Scientific Advisory Panel (SAP) meeting in which the panel strongly encouraged OPP to develop and validate tools and methodologies to conduct probabilistic assessments of ecological risk, no mention of the SAP recommendation can be found in the EFED science chapter. We believe this is a significant shortcoming of the science chapter since foremost among the suggestions offered by the SAP was that the Office of Pesticide Programs (OPP) move beyond the present single point deterministic process of risk assessment originally established as a first tier screening tool. Thus, the EFED science chapter conclusions which are primarily based on deterministic risk assessment procedures (i.e., LD_{50}/ft^2) are rudimentary in light of the SAP's suggestion to address the magnitude of the expected impact of exposure as well as the uncertainty and variation involved.

A task force called the Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM) composed of industry, government, and private sector experts is actively working on the development of the probabilistic methodologies recommended by the SAP to assess risk. We respectfully suggest that conclusions regarding the ecological risk associated with phorate use cannot be accurately drawn until the scientifically-sound,

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peer reviewed risk assessment methodologies being composed by ECOFRAM are in place.

Non-target organism incident reporting may provide risk managers with important information if properly interpreted. The draft EFED science chapter mentions 15 bird kills all of which resulted from the misuse of phorate or under unusual or unknown circumstances as previously documented in correspondence to EPA and U.S. Fish and Wildlife Service. When compared with the Risk Quotient (RQ) derived from the LD_{50}/ft^2 value, this lack of widespread and repeated avian incidents (considering the extensive use of the product since the late 1950's) further supports the SAP's contention that deterministic assessments are of limited value in evaluating the true ecological risk of a compound.

A central theme in risk assessment which is oftentimes forgotten is that risk is a product of toxicity and exposure. While laboratory data indeed show that phorate is highly toxic to non-target organisms, a true degree of exposure is not factored into the equation. The incident data for phorate mentioned above indicate that exposure is not as great as predicted by the deterministic model.

Phorate, an organophosphate compound with a short environmental half life, has been used by American farmers for approximately 40 years with millions of pounds applied annually to protect key crops such as corn, cotton, peanuts, and potatoes. EPA risk managers should take into consideration potentially losing one of the few generically available, consistently effective broad spectrum soil insecticides based on a decision driven by risk assessment procedures considered inappropriate by the Agency's own Scientific Advisory Panel.

Please contact me directly at telephone number 609-716-2378 should you have any questions.

Sincerely,

John J. Wrubel
Product Registrations Manager
U.S. Plant Regulatory Affairs

cc: M. Mautz, OPP/RD/IRB/Team 14
A. Baldi, Aceto Agricultural Chemicals Co.

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